K014127

MAR 1 5 2002

510(k) Summary

Innovation In Motion's
510(k) Premarket Notification
Karma Discovery Series Power Wheelchair

Submitter's Name, Address, Telephone, Fax Number, Contact Name

Karma Medical Products, Co., LTD.
No. 29 Cheng-Kung First Street
Min-Hsiung Industrial Zone
Chia-Yi Hsien, 621. Taiwan
Phone: 886 5 221 1996 Fax: 886 5 221 1965

Manufacturer's Name, Address, Telephone, and Fax Numbers

Karma Medical Products, Co., LTD.
No. 29 Cheng-Kung First Street
Min-Hsiung Industrial Zone
Chia-Yi Hsien, 621. Taiwan
Phone: 886 5 221 1996 Fax: 886 5 221 1965

Name of Device

Karma Discovery Series Power Wheelchair

Name of Applicant/Submission Correspondent, Address, Phone, Fax Numbers, and Contact Name:

Innovation In Motion
900 Growth Parkway
PO Box 507
Angola, IN 46703
Phone 219.668.5677 Fax: 219.668.8967
Rick Michael – rick@vestil.com

Date Prepared

December 2001

Common or Usual Name
Power Wheelchair

Classification Name
Wheelchair, Power

Predicate Devices
The product that is substantially equivalent to the Discovery is Invacare's Ranger X rear wheel drive power wheelchair (K852811).

Intended Use
The intended use of the Discovery rear wheel drive power wheelchair is to provide mobility to persons limited to a sitting position who have the capability of operating a power wheelchair.

Technological Characteristics and Substantial Equivalence

Device Description:

The Discovery power wheelchair is a battery powered, motorized mobility vehicle. The intended use of the Discovery rear wheel drive power wheelchair is to provide mobility to persons limited to a sitting position who have the capability of operating a power wheelchair.

The Discovery is designed to be durable, dependable, sporty and aesthetically appealing while being economically priced.

Substantial Equivalence:

The product that is substantially equivalent to the Discovery rear wheel power wheelchair is Invacare's Ranger X power wheelchair (K852811).

Both of these products are battery powered wheelchairs with the same intended function and use-- the provision of mobility to persons limited to a sitting position that have the capability of operating a powered wheelchair. Similarities include large wheels with attached motor/gearbox drive mechanisms, smaller pivoting casters for turning, and joystick operated motor controllers to engage system motion and steer the wheelchair. They are all constructed from the same basic materials, have the same basic operational principles, and all use DC batteries as their source of power.

Performance Data:

As required by FDA's July 26, 1995 draft publication entitled "Guidance Document for the Preparation of Premarket Notification [510(k)] Application for Mechanical and Powered Wheelchairs, and Motorized Three –Wheeled Vehicles", the Discovery Power Wheelchair was tested in accordance with ISO/CD 7176-21 and the ANSI/RESNA Vol.2 Section 21 Amendments for powered wheelchairs and motorized scooters. In all instances, the Discovery Power Wheelchair met the required performance criteria and functioned as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2002

Mr. Rick Michael
North American Sales Manager
Vestil Manufacturing Corporation
900 Growth Parkway
Angola, Indiana 46703

Re: K014127
Trade/Device Name: Karma Discovery Series Power Wheelchair
Regulation Number: 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: December 14, 2001
Received: December 17, 2001

Dear Mr. Michael:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

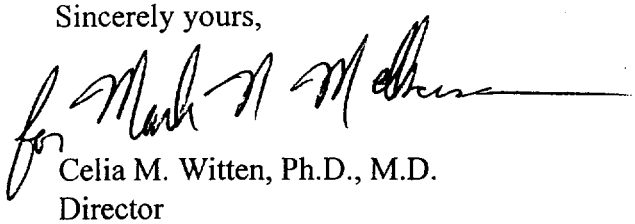
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: Innovation In Motion

Submitter: Karma Medical Products

Name of Device: Karma Discovery Series Power Wheelchair

510(k) Number (if known): K014127

Device Name: Power Wheelchair

Indications For Use:

The intended use of the Discovery rear wheel drive power wheelchair is to provide mobility to persons limited to a sitting position who have the capability of operating a power wheelchair.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014127

Prescription Use____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96